

Applicants: David Pinsky, David Stern and Shi-Fang Yan  
Serial No.: 09/648,389  
Filed: August 25, 2000  
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REMARKS

Claims 16 and 18-36 are pending and under examination in the subject application. By this Amendment, applicants have amended claims 16, 20, 26-30 and 36, and canceled claims 21 and 31 without prejudice or disclaimer. The amendments are merely to introduce certain format changes. Applicants maintain that this Amendment raises no issue of new matter. Accordingly, upon entry of this Amendment, claims 16, 18-20, 22-30 and 32-36 will be pending and under examination.

Rejection under 35 U.S.C. §112, Second Paragraph

The Examiner rejected claims 16, 27 and 31 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, the Examiner alleges that claims 16 and 27 are indefinite because they recite the limitation "vascular tissue", and that there is insufficient antecedent basis for this limitation in the claim because the claims earlier recite "ischemic tissue".

Without conceding the correctness of the Examiner's rejection, applicants direct the Examiner's attention to amended claim 16, which now includes the phrase "vascular tissue injury". Applicants assert that there is now sufficient antecedent basis for this limitation. Accordingly, claim 27, which depends on claim 16,

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also contains sufficient antecedent basis for the limitation.

The Examiner further alleges that claim 31 is indefinite because it recites the term "fragment thereof", which follows a peptide, a peptidomimetic compound, a nucleic acid molecule, a small molecule, an organic compound, and inorganic compound or an antibody. The Examiner alleges that it is unclear how "a fragment thereof" applies to a peptidomimetic compound, an organic compound or an inorganic compound. Furthermore, the Examiner alleges that it is unclear whether the "fragment thereof" is a fragment of a peptide, a nucleic acid molecule, a small molecule or an antibody.

Without conceding the correctness of the Examiner's rejection, applicants have herein canceled claim 31. Accordingly, the Examiner's rejection of claim 31 is now moot.

In view of the above remarks, applicants maintain that claims 16 and 27 satisfy the requirements of 35 U.S.C. §112, first paragraph.

#### **Rejection under 35 U.S.C. §112, First Paragraph**

The Examiner also rejected claims 16 and 18-36 under 35 U.S.C. §112, first paragraph.

Specifically, the Examiner alleges that while the specification is enabling for a method for reducing ischemic damage to a tissue being transplanted into a subject comprising contacting the tissue with SEQ ID. NO. 1 ex vivo, it does not reasonably provide

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enablement for a method of reducing ischemic damage to tissue being transplanted into a subject comprising contacting the tissue with any inhibitor of Egr-1 *ex vivo*.

Without conceding the correctness of the Examiner's rejection, applicants have canceled claims 21 and 31. Accordingly, the examiner's rejection of these claims is now moot.

Applicants also direct the Examiner's attention to amended claim 16, which recites a "*nucleic acid* which inhibits expression of Early Growth Response Factor-1 (Egr-1) protein..." and amended claim 28, which recites a "*nucleic acid* that inhibits Early Growth Response Factor-1 (Egr-1)..." [emphasis added]. Applicants maintain that the specification is enabling for methods of inhibiting Early Growth Response Factor-1 (Egr-1) using a nucleic acid.

The Examiner further alleges that the instant specification does not enable an *in vivo* method for reducing vascular injury during reperfusion of an ischemic tissue comprising contacting the tissue with a nucleic acid comprising a polynucleotide sequence complementary to Egr-1.

Applicants respectfully traverse the Examiner's position. The Examiner concedes that the instant specification is enabling for a method of reducing ischemic damage to tissue *ex vivo* comprising contacting the tissue with a nucleic acid having SEQ ID NO. 1. Applicants maintain that damage to the vascular tissue of an

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ischemic tissue would similarly be reduced when a nucleic acid contacts said tissue *in vivo*. Indeed, the cells in question -- i.e., blood vessel cells -- exist in tissue form *ex vivo*, as opposed to free-floating cell culture form, rendering them a more structurally and physiologically accurate model for predicting *in vivo* results. Furthermore, because the tissue being contacted with the nucleic acid is vascular, intravenous administration of the nucleic acid would necessarily contact the vascular tissue. The Examiner has not provided any evidence indicating that the favorable results obtained with *ex vivo* vascular tissue treatment with Egr-1 would differ from results obtained with *in vivo* treatment.

In view of the above remarks, applicants maintain that claims 16 and 18-36 satisfy the provisions of 35 U.S.C. §112, first paragraph.

#### Summary

In view of the remarks made herein, applicants maintain that the claims pending in this application are in condition for allowance. Accordingly, allowance is respectfully requested.

If a telephone interview would be of assistance in advancing the prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

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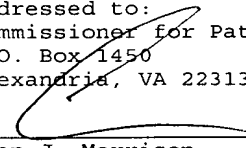
No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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 11/10/03  
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